

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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SAVANNAH SMITHSON,	*	
	*	No. 13-735V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: April 9, 2019
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

* * * * *

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner;
Lara A. Englund, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DISMISSING PETITION¹

Ms. Smithson filed her claim for compensation on September 25, 2013.² Ms. Smithson claimed that HPV vaccines she received on November 5, 2012, and February 4, 2013, caused her to develop adrenal deficiency and dysautonomia, which presented as postural orthostatic tachycardia syndrome (POTS). In the years since 2013, Ms. Smithson has had the opportunity to present reports from numerous experts and treating physicians in support of her claim of compensation. However, the reports submitted have continued to struggle to provide preponderate

¹ Because this ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the ruling.

² Savannah Smithson's claim was initially filed by her parents, Chuck and Rhonda Smithson. Savannah was substituted as petitioner after reaching the age of majority in Arizona. See order, issued April 26, 2017.

evidence of an association between Ms. Smithson's vaccinations and the injuries she alleged. On April 2, 2019, Ms. Smithson moved to dismiss her petition, citing her conclusion that "she will likely be unable to meet her burden of proof and establish that she is entitled to compensation in the Vaccine Program." Because the undersigned finds that Ms. Smithson has been provided a full and fair opportunity to present her claim of compensation and agrees with her conclusion that she cannot prevail on her petition based on the evidence in the record, Ms. Smithson's motion is GRANTED and her petition is DISMISSED for insufficient proof.

Brief Factual and Procedural History

Petitioner filed her statement of completion on October 21, 2013. Shortly thereafter, respondent filed a status report identifying records that remained outstanding. Resp't's Status Rep., filed Nov. 19, 2013, at 1-3. Petitioner filed the outstanding records by February 14, 2014.

Once the record was sufficiently complete, the Secretary opposed Ms. Smithson's eligibility for compensation under the Vaccine Act. See Resp't's Rep., filed April 9, 2014, at 10-17. The Secretary argued that the evidence did not support the conclusion that Ms. Smithson had the condition she alleged and, furthermore, even if she did, it could not be and was not caused by her HPV vaccines. Id.

Petitioner filed a brief expert report from Dr. Ramesh Adiraju, a cardiologist, in support of her claim for compensation on July 11, 2014. Exhibit 14. Dr. Adiraju's report was incomplete and not persuasive. See order, issued July 25, 2013, at 1. Petitioner filed a supplemental report from Dr. Adiraju on August 15, 2014. Exhibit 16. Dr. Adiraju's supplemental report was also deficient and, furthermore, highlighted the need for an immunologist to supplement Dr. Adiraju's conclusions. See order, issued Sept. 8, 2014, at 1.

Petitioner filed an expert report from Dr. David Axelrod, an immunologist, and a second supplemental report from Dr. Adiraju, on October 13, 2014 and October 21, 2014, respectively. Exhibit 22; exhibit 31. Respondent requested and was granted the opportunity to submit responsive reports. Order, issued Nov. 5, 2014.

Respondent filed expert reports from Dr. Kenneth Mack, a pediatric neurologist, and Dr. Arnold Levinson, an immunologist, on February 9, 2015.

Exhibit A; exhibit C. Perhaps most saliently, both experts noted that there was a gold-standard test for POTS, a tilt-table test, and that Ms. Smithson had not been diagnosed using that procedure. Exhibit A at 3; exhibit C at 5. The undersigned suggested that the parties contact Ms. Smithson's treating physicians to elicit their opinions on the correct diagnosis. See order, issued Feb. 12, 2015. The parties were amenable to this approach and agreed to draft a joint letter. Id.

In the following months, petitioner filed responsive letters from two of Ms. Smithson's treating physicians: Dr. Michael Gerber and Dr. Stewart Tatem. Exhibit 32; exhibit 34. Dr. Gerber's letter stated that Ms. Smithson was diagnosed with POTS, though did not reference the diagnostic criteria used, and Dr. Tatem's letter indicated that Ms. Smithson had had signs consistent with POTS (i.e., elevated heart rate) but did not provide a first-hand account of having diagnosed her with the condition. Id. Petitioner requested, and was granted, leave to proceed with responsive reports from her expert witnesses. Order, issued June 30, 2015, at 4. The petitioner's experts were provided with detailed instructions for how to address the elements of Ms. Smithson's case. Id. at 1-4.

Petitioner did not proceed with reports from her original two experts, Dr. Adiraju and Dr. Axelrod, but instead provided a report from Dr. Patrick Nemechek, an internal medicine specialist. Exhibit 39. The undersigned raised several concerns about deficiencies in Dr. Nemechek's report and granted petitioner leave to have Dr. Nemechek prepare a supplemental report to address these concerns. Order, issued Sept. 16, 2015, at 1-3. Dr. Nemechek was especially encouraged to address Ms. Smithson's pre-vaccination state, the lack of tilt-table testing with regards to her diagnosis, and the appropriate timing between the vaccine and the onset of dysautonomia under her proposed theory of causation. Id. The undersigned also ordered petitioner to supplement Dr. Adiraju and Dr. Axelrod's reports to address the previously-identified deficiencies in the case that petitioner intended to rely on either of their reports at a hearing. Id.

In a status report filed on December 2, 2015, petitioner stated that she intended to proceed with Dr. Nemechek as her only witness and would not rely on the reports submitted by Dr. Adiraju and Dr. Axelrod. On December 2, 2015, petitioner filed the supplemental report from Dr. Nemechek. Exhibit 110. During a status conference on January 19, 2016, the undersigned communicated various concerns about the contents of Dr. Nemechek's reports and his failure to address various elements of petitioner's claim for compensation. See order, issued Jan. 27, 2016.

After multiple enlargements of time were requested and granted, respondent filed responsive reports from both Dr. Mack and Dr. Levinson on August 22, 2016. Exhibit E; exhibit G. Both reports were, persuasively, critical of Dr. Nemechek's most recent report, noting numerous instances where Dr. Nemechek made conclusions based on facts not in the record and relied on inferences that were not scientifically plausible. See id.

Following the submission of respondent's expert reports in August 2016, efforts were undertaken by petitioner and her expert, Dr. Nemechek, to perform diagnostic testing on Ms. Smithson that would be able to show that she suffered from dysautonomia. See order, issued Sept. 15, 2016. Petitioner filed the results of this testing on January 10, 2017. Exhibit 125. This testing, which was performed by Dr. Nemechek, alleged showing that Ms. Smithson suffered from "substantial parasympathetic damage" and "inadequate sympathetic function." Id. While the results of the autonomic testing were potentially relevant and helpful, it was noted during the February 7, 2017 status conference that Dr. Nemechek's report had failed to address the concerns raised by respondent's expert in his most recent report. Order, issued Feb. 7, 2017. Petitioner was offered an opportunity to supplement Dr. Nemechek's expert report. Id. In a status report filed on April 3, 2017, petitioner stated that she had "conferred with Dr. Nemechek and determined that no additional report from Dr. Nemechek is needed or will be forthcoming." She further noted that the concerns raised by respondent's expert would "be addressed in pre-hearing briefing." On May 16, 2017, Ms. Smithson's petition was set for a three-day hearing to be held May 21, 2018 to May 23, 2018, in Washington, D.C.

Three months before the hearing was scheduled to occur, petitioner requested a status conference. During the status conference, held on February 22, 2018, petitioner stated that she was no longer confident in her expert's ability to opine in support of her claim for compensation. Order, issued Feb. 23, 2018. As a result, petitioner requested that the hearing be cancelled so that she could obtain an expert report from a new expert. Id. Petitioner's request was granted, and petitioner was given until April 27, 2018 to file a report from a new expert witness.

Petitioner filed an expert report from her fourth, and final, expert, Dr. Mitchell Miglis, on April 3, 2018. Exhibit 127. A status conference was held on May 8, 2018, to discuss Dr. Miglis' report. During the status conference, petitioner was ordered to have Dr. Miglis supplement his initial report with additional information on the diagnostic testing used to diagnose Ms. Smithson with dysautonomia and furthermore to state the basis for his association of the

HPV vaccine and dysautonomia. Order, issued May 9, 2018. Petitioner filed a supplemental report from Dr. Miglis on July 16, 2018. Exhibit 141. During a status conference on October 16, 2018, the undersigned emphasized that while Dr. Miglis had provided some evidence to conclude that POTS has an autoimmune etiology, there did not appear to be support for his conclusion that the HPV vaccine could cause the autoimmune process that would give rise to POTS. Order, issued Oct. 17, 2018, at 1.

Respondent filed a final set of reports from Dr. Levinson and Dr. Mack on November 9, 2018. Exhibit H; exhibit I.

During a November 29, 2018 status conference to discuss next steps, the undersigned communicated concerns about petitioner's case. Most importantly, the undersigned noted that "without evidence associating the HPV vaccination to POTS, Ms. Smithson cannot be awarded compensation." Order, issued Nov. 29, 2018, at 1 (citing Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012)). The undersigned identified a recent decision by Special Master Corcoran that evaluated claims very similar to petitioner's and indicated that the analysis by Special Master Corcoran appeared to be sound. Id. at 2 (citing Johnson v. Sec'y of Health & Human Servs., No. 14-254V, 2018 WL 2051760, at *37-41 (Fed. Cl. Spec. Mstr. Mar. 23, 2018)). Petitioner requested, and was granted, time to consult with her attorney and consider her next steps. Id. at 2.

On April 2, 2019, petitioner filed the present motion for her petition to dismissed.

Analysis and Conclusion

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). In other words, Ms. Smithson must prove that, more likely than not, that she was injured by her vaccinations.

The facts of Ms. Smithson's case do not allow the undersigned to find that the evidence preponderates in favor of Ms. Smithson's claim that her vaccinations

caused her to develop dysautonomia, POTS, or any related conditions. As noted throughout the pendency of this proceeding, the evidence submitted by Ms. Smithson failed to provide persuasive evidence supporting her claim that HPV vaccinations *can* cause dysautonomia, POTS, or any other underlying autoimmune disorder she may suffer from. Furthermore, the evidence failed to establish that the vaccinations *did* cause the conditions she alleges she suffers from.

For these reasons, the undersigned finds that Ms. Smithson has been provided a full and fair opportunity to present her case of a vaccine injury. Furthermore, the undersigned finds that the evidence entered by Ms. Smithson is not sufficient to meet her statutory burden for proving a compensable vaccine injury. Accordingly, Ms. Smithson's petition is DISMISSED pursuant to Vaccine Rule 8(d).

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master